REMARKS/ARGUMENTS

Upon entry of this amendment, new claims 13-17 will be pending in the application and presented for examination. Claims 1-12 have been canceled without prejudice. Claims 13-17 have been added. Entry of the amendment and allowance of claims 13-17 are respectfully requested.

The Amendment

In order to expedite prosecution of the application and advance the case toward allowance, the claims have been canceled and new claims have been added. No new matter was introduced by this amendment.

Claim 13 has been added according to the Examiner's suggestion (see page 10 of the Office Action; new claim 13). The Office Action indicates that this claim is supported and likely allowable. The Applicants gratefully acknowledge the Examiner's suggested amendment.

Claim 14 has been added and specifies that the antibody is a monoclonal antibody. Support can be found in the specification (and priority documents) and references cited in the specification and incorporated therein. For example, page 7 of the specification lists a number of references that are well known in the art including *Methods in Enzymology,* Volumes 154 and 155 (Wu and Grossman, and Wu, Eds., respectively), (Mayer and Walker, Eds.) (1987); *Immunochemical Methods in Cell and Molecular Biology* (Academic Press, London), Scopes, (1987); and *Handbook of Experimental Immunology,* Volumes I-IV (D. M. Weir and C. C. Blackwell, Eds 1986). Specifically, the term "monoclonal antibody" is supported, for example, throughout Chapter 13, pages 13.1-13.13, of Volume 1 of the *Handbook of Experimental Immunology,* (D. M. Weir and C. C. Blackwell, Eds 1986). Copies of the specific pages of the supporting references are attached as Appendix A.

Claim 15 has been added and specifies that the antibody is a Fab antibody fragment. The term "binding fragment" is supported, for example, on page 8 of the specification, paragraph 0018, wherein the MCP-1 antagonists (*e.g.,* antibodies) and fragments thereof are discussed. Furthermore, a binding fragment such as a Fab antibody fragment is supported, for example, on page 11.2 and throughout Chapter 14, pages 14.1-14.23 of Volume 1 of the

Handbook of Experimental Immunology, (D. M. Weir and C. C. Blackwell, Eds 1986) which is incorporated by reference into the specification on page 7 (*supra*). Copies of the specific pages of the supporting references are attached as Appendix B.

Claim 16 has been added and defines a composition that comprises the antibody of claim 13 and a pharmaceutical carrier. A "composition" and a "pharmaceutical carrier" are supported, for example, on page 8, paragraph 0018 of the specification.

Claim 17 has been added and specifies a method of making an antibody that binds MCP-1 receptor polypeptide comprises immunizing an animal with the polypeptide comprising SEQ ID NO: 2; and isolating the antibody. Support for this amendment can be found, for example, on page 7, paragraph 0015 in the references that are incorporated by reference into the specification. Specifically, pages 108.2-108.5 of Volume 4, Chapter 108 of the *Handbook of Experimental Immunology,* for example, teach how antibodies can be made and isolated. Copies of the specific pages of the supporting references are attached as Appendix C.

Priority

The Office Action alleges that this application adds additional disclosure not presented in prior applications. However, the specification of this application is identical to the specifications of the prior filed U.S. Application Nos. 09/625,573 (filed 7/25/00) and 08/446,669 (filed 5/25/95) as well as the 371 National Stage Application PCT/US95/00476 (filed 1/11/95). The PCT/US95/00476 Application is a CIP of U.S. Application No. 08/182,962 which was filed on January 13, 1994. As such, the earliest priority date of this application is January 13, 1994.

Rejection under 35 U.S.C. §112

Claims 1-5 and 9-12 are rejected under 35 U.S.C. §112, first paragraph, for allegedly lacking written description. The Office Action alleges that no support can be found in the specification for a number of recited claim limitations.

Although, claims 1-12 have been canceled and new claims 13-17 have been added, the rejection is still respectfully traversed.

"An objective standard for determining compliance with the written description requirement is, '[D]oes the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed.' *In re Gosteli,* 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989). Under *Vas-Cath, Inc. v. Mahurkar,* 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991), to satisfy the written description requirement, an applicant must convey **with reasonable clarity** to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention, and that the invention, in that context, is whatever is now claimed." (MPEP 2163.02) [emphasis added]

Claim 13 would be understood to encompass many different kinds of antibodies, including monoclonal antibodies, polyclonal antibodies, humanized antibodies, Fab antibody fragments, Fc antibody fragments, *etc.* The Examiner must appreciate that the term "antibody" would have been understood by those of skill in the art at the time of the invention to encompass all the different binding entities listed above. This information has been available to those of skill for a considerable period of time and the skilled artisan would certainly understand that the term "antibody" includes all of those binding entities. The Examiner is invited to review the attached references from 1986 to see that the art was generally well informed about different antibody binding entities and the methods of how to employ them.

In addition, the dependent claims are supported by the specification as filed. The Examiner alleges that specific terms have no support in the present application or the priority documents and constitute new matter. However, each of the terms cited by the Examiner is clearly supported in the specification (and priority documents) and references cited in the specification and incorporated therein. As mentioned above, page 7 of the specification lists a number of references that are well known in the art including *Methods in Enzymology,* Volumes 154 and 155 (Wu and Grossman, and Wu, Eds., respectively), (Mayer and Walker, Eds.) (1987); *Immunochemical Methods in Cell and Molecular Biology* (Academic Press, London), Scopes, (1987); and *Handbook of Experimental Immunology,* Volumes I-IV (D. M. Weir and C. C. Blackwell, Eds 1986). See Appendices A-C.

The term "binding fragment" is supported, for example, on page 8 of the specification, paragraph 0018, wherein the MCP-1 antagonists (*e.g.,* antibodies) and fragments

thereof are discussed. Furthermore, a binding fragment of an antibody such as a Fab antibody fragment is supported, for example, on page 11.2 and throughout Chapter 14, page 14.1-14.23 of Volume 1 of the *Handbook of Experimental Immunology,* (D. M. Weir and C. C. Blackwell, Eds 1986) which is incorporated into the specification by reference (*supra*).

Further and as indicated above, the term "monoclonal antibody" is supported, for example, throughout Chapter 13, pages 13.1-13.13, of Volume 1 of the *Handbook of Experimental Immunology,* (D. M. Weir and C. C. Blackwell, Eds 1986). See Appendix A. A "method of making an antibody" is supported, for example, on pages 108.2-108.5 of Chapter 108, Volume 4 of the *Handbook of Experimental Immunology,* (D. M. Weir and C. C. Blackwell, Eds 1986). See Appendix C. A "composition" is supported, for example, on page 8, paragraph 0018 of the specification. Thus, the specification and references incorporated therein provide ample support for antibodies and fragments thereof as well as methods of making them.

Claims 1-12 have been canceled. Thus, the rejection of claims 1-5 and 9-12 under 35 U.S.C. §112, first paragraph, for allegedly lacking written description, is moot.

Claims 1 and 11 are rejected under 35 U.S.C. §112, first paragraph, for allegedly lacking enablement. Specifically, the Examiner indicates that the specification is not enabling for antigen binding fragments and/or neutralization of activity of the MCP-1 receptor because the specification does allegedly not teach which fragments can be used such that requisite functionality is maintained.

Although, claims 1-12 have been canceled and new claims 13-17 have been added, the rejection is still respectfully traversed.

As the Examiner is aware of, the courts have repeatedly held that a "patent need not teach, and preferably omits, what is well known in the art" (*Lindemann Maschinenfabrik GMBH v. American Hoist and Derrick Company et al.,* 221 USPQ 481 (Fed. Cir. 1984)). In fact, recent case law reemphasizes that the inventor must not teach what is already known in the art. In *Chiron Corporation v. Genentech Inc.* (363 F.3d 1247, 70 U.S.P.Q.2d 1321 (Fed. Cir. 2004)), the Federal Circuit held that "a patent disclosure need not enable information within the knowledge of an ordinarily skilled artisan. Thus, a patentee preferably omits from the disclosure

any routine technology that is well known at the time of application." (Citing *Hybritech,* 802 F.2d at 1384.) Hence, the Applicants are not required to teach what is well know in the art such as routine methods of characterizing, isolating and making antibodies and Fab antibody fragments. Furthermore, the "test of enablement is not whether any experimentation is necessary, but whether, if experimentation is necessary, it is undue" (*In re Angstadt,* 537 F.2d 498, 504, 190 USPQ 214, 219 (CCPA 1976).

Claims 1 and 11 have been canceled. New claim13 has been added according to the Examiner's suggestion and is now drawn to an antibody which specifically binds MCP-1 receptor polypeptide, wherein the polypeptide comprises the amino acid sequence of SEQ ID NO: 2. In addition, new dependent claim 15 specifies that the antibody can be a Fab antibody fragment.

As mentioned above, the term "antibody" would have been understood by those of skill in the art at the time of the invention to encompass several different binding entities including Fab antibody fragments, Fc antibody fragments, monoclonal antibodies, polyclonal antibodies, *etc.* In fact, the use of an antibody or fragment thereof was considered a routine procedure at the time of filing. Notably, all the terms referred to in the claims (*e.g.,* monoclonal antibody, Fab antibody fragment, *etc.*) are clearly understood by anyone of average skill in the art to be included in the term antibody. For example, the skilled artisan is well aware that a Fab antibody fragment contains the antigen-binding site and is generated by cleavage of the antibody with an enzyme (*e.g.,* papain). As previously indicated, a Fab antibody fragment is supported on page 11.2 and throughout Chapter 14, page 14.1-14.23 of Volume 1 of the *Handbook of Experimental Immunology,* (D. M. Weir and C. C. Blackwell, Eds 1986) which is incorporated in the specification. Specifically, pages 14.16-14.17 teach how Fab antibody fragments can be isolated from papain digests and purified. Because Fab antibody fragments are so well known in the art and their use is considered perfectly routine, the skilled artisan would have no difficulty practicing the invention as now claimed. Thus, in light of the teachings of the instant specification and the guidance provided by the references incorporated therein, no undue experimentation would be required to produce an antibody that specifically binds MCP-1 receptor polypeptide comprising SEQ ID NO: 2 and/or a Fab antibody fragment thereof.

Since claims 1 and 11 have been canceled, the rejection under 35 U.S.C. §112, first paragraph, for allegedly lacking enablement, is moot.

Rejection under 35 U.S.C. §102(b)

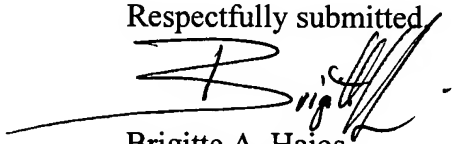
Claims 1-5 and 9-12 are rejected under 35 U.S.C. §102(b), for allegedly being anticipated by Wang *et al.*, U.S. Patent No. 6,723,520, filed January 3, 2002 and issued April 20, 2004.

Claims 1-12 have been canceled and the rejection is moot. However, it is stated for the record that since Wang *et al.* was issued on April 20, 2004 and the instant application has a priority date of January 11, 1995, Wang *et al.* never qualified as a reference under 35 U.S.C. §102(b).

CONCLUSION

In view of the foregoing, Applicants believe that new claims 13-17 now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

Respectfully submitted,



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Enclosures: Appendices A-C

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